UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, *et al.*, Plaintiffs, *Ex rel.*, JAMIE SIEGEL, M.D., Plaintiff-Relator, v. NOVO NORDISK, INC., Defendant.	CASE NO. C23-5459 BHS ORDER

THIS MATTER is before the Court on plaintiffs Siegel and Washington's motion to exclude the testimony of defendant Novo Nordisk's expert witness, Daniel Troy, Dkt. 415. Troy has been an attorney for 40 years, with 23 years of experience in health care regulation, including three years as Chief Legal Counsel to the FDA and many more in the private sector health industry. Novo Nordisk (NNI) contends he is a scholar who has

studied FDA's regulatory framework governing communications about off label uses of prescription drugs (including pharmaceutical manufacturer involvement in the development and dissemination of peer-reviewed clinical publications), as well as the provision of drug samples to physicians. Dkt. 441 at 2.

Washington does not challenge Troy's credentials or expertise. Instead, it asserts that his Report reads like a legal brief, and challenges the admissibility of his proffered legal conclusions: that NNI's conduct "*could be* consistent with the First Amendment and FDA guidance," and that its distribution of free samples "*can be* consistent with FDA regulations." Dkts. 415 at 1; 466 at 2 (citing Troy's Report, Dkt. 416-1 at 10) (emphasis added). Washington argues that Troy's opinions are improper legal conclusions about the ultimate issue of law: whether NNI's marketing practices are protected by the First Amendment or FDA regulations. It argues that "can be" is not an opinion at all; it is speculation. Washington contends that Troy's testimony would confuse and mislead the jury about the legality of NNI's practices, prejudicing it. Dkt. 415 at 2.

A qualified expert may testify in the form of an opinion or otherwise only if the proffered testimony is both relevant and reliable. Fed. R. Evid. 702; *Teradata Corp. v. SAP SE*, 124 F.4th 555, 566 (9th Cir. 2024) (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993)).

Rule 702 and *Daubert* impose on the district court a "gatekeeping" duty to ensure that opinion testimony is relevant and reliable, and an expert's opinion should be excluded if it does not have a reliable foundation or if it is not based in the knowledge and experience of the relevant discipline. *Sonneveldt v. Mazda Motor of Am., Inc.*, 2024

U.S. App. Lexis 32836, *3 (9th Cir. Oct. 21, 2024) (citing *Primiano v. Cook*, 598 F.3d 558, 564-65 (9th Cir. 2010)). "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Surgical Instrument Serv. Co. v. Intuitive Surgical, Inc.*, 2024 U.S. Dist. Lexis 81690, *5 (N.D. Cal. March 31, 2024) (quoting *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 739 F.3d 960, 969 (9th Cir. 2013). When an expert meets the Rule 702 threshold the expert may testify, and the jury decides how much weight to give that testimony." *Primiano*, 598 F.3d at 565.

Washington concedes that, as a general rule, an expert's opinion is not objectionable simply because it embraces an ultimate issue to be decided by the trier of fact. Dkt. 413. at 11 (citing Fed. R. Evid. 704(a)). But it argues persuasively that an expert cannot opine as to a legal conclusion, or to the ultimate issue of law. This is so because instructing the jury on the applicable law is the Court's distinct and exclusive province. *Id*. (citing *Nationwide Transp. Fin. v. Cass Info. Sys.*, 523 F.3d 1051, 1058 (9th Cir. 2008); and *Pelican Int'l, Inc. v. Hobie Cat Co. II, LLC*, 655 F. Supp. 3d 1002, 1031 (C.D. Cal. 2023) ("It is well-established that an expert witness may not explain the law to the jury or tell the jury how to apply the law to the facts of the case. . . . Thus, expert testimony must be circumscribed carefully to ensure that the expert does not usurp … the role of the trial judge in instructing the jury as to the applicable law.") (internal quotations and citations omitted)). It argues that Courts have broad discretion to exclude opinions that consist of improper legal conclusion and opinions regarding governmental

regulations and policies. *Id*. at 7 (citing *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1052-53 (9th Cir. 2012)).

NNI responds there is well-established precedent that a properly qualified expert with expertise in the regulatory framework or landscape of a highly technical and regulated industry or program, such as Medicaid, can help a jury understand the evidence or determine a fact in issue. It argues that far from unduly prejudicing Washington or confusing the jury, Troy's testimony will assist the jury in understanding the FDA's enormously complex regulatory structure, in order to evaluate whether NNI's conduct was improper. Dkt. 441 at 2–3.

The Court agrees with NNI that the bulk of Troy's testimony will assist the jury and is admissible. This case presents a complexity of issues that requires the jury to understand the regulatory scheme of the government's oversight of pharmaceuticals through the review of extensive legal briefing spanning the years that this litigation has been pending. If a jury is expected in a matter of days to comprehend and understand how the facts as presented fit within the regulatory framework, the Court values competent and qualified witnesses who can perform this function. The Court will allow Troy's testimony to provide what in essence is a tutorial on this framework.

However, Troy will not be allowed to testify on how the application of the First Amendment has informed the development of case law in America as it applies to the pharmaceutical industry in its testing and promotion of its drugs.

Troy will be permitted to testify about the marketing role that the dissemination of peer-reviewed studies has in the medical industry for the purpose of acquainting

practicing physicians with new pharmaceuticals or new treatment applications of established pharmaceuticals, including off-label uses. He is further qualified to testify about how off-label uses can be the standard of care for some drugs and some uses.

Troy's testimony should discuss industry and regulatory standards when assessing a specific study or article, including the use of the FDA's nonbinding *Good Reprint Practice* guidance, and related recommendations.

Troy devotes a significant part of his report to discussing the *Konkle Study* in the context of the *Good Reprint Practice* review. This was apparently chosen because Washington cited it as an example of a marketing violation of the AKS.

As a defense expert, the Court reviews Troy's report and his expected trial testimony as rebuttal testimony. Troy will be permitted to go through the *Good Reprint Practice* guidance and review the record by identifying what NNI did factually to meet the Guidance standards. He will not be permitted to testify that NNI's activities in connection with the *Konkle Report* rendered NNI in compliance with the AKS "safe harbor" as this would be testimony an ultimate issue of law.

In the Court's view, Troy's testimony is not unlike that of an expert physician specialist explaining to a jury the standard of care for a particular procedure by describing the procedure's steps and then explaining, through reference to the medical records, what steps the allegedly negligent physician took. The expert would not be permitted to testify that, in his opinion, the reviewed physician was or was not negligent.

Similarly, Troy will be permitted to rebut any evidence produced in Washington's case in chief regarding its claim that the jury should make a negative inference from the

fact NNI rejected the FDA's request that NNI conduct a Phase III Study. He describes these studies as expensive and explains how other alternatives can be used to demonstrate that NovoSeven is safe and effective, what he calls "real world evidence."

Troy will also be permitted to rebut any evidence Washington introduces about free drug samples. He can describe how the FDA regulates this activity, and under what conditions free samples can meet the AKS's safe harbor requirements, and what the record demonstrates about NNI's distribution of free samples. He may not testify that NNI complied with the regulations relating to free samples.

Washington's Daubert motion to exclude Troy's testimony, Dkt. 415, is **GRANTED** in part and **DENIED** in part.

IT IS SO ORDERED.

Dated this 14th day of July, 2025.

BENJAMIN H. SETTLE
United States District Judge